DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 20, 2015

Vital Art and Science, LLC.
c/o Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K143211
Trade/Device Name: myVisionTrack® Model 0005
Regulation Number: 21 CFR 886.1330
Regulation Name: Amsler grid
Regulatory Class: Class I
Product Code: HOQ
Dated: February 13, 2015
Received: February 18, 2015

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, MD
Director,
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
myVisionTrack® Model 0005

Indications for Use *(Describe)*
The myVisionTrack® Model 0005 is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring progression of disease factors causing metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home. The myVisionTrack® Model 0005 is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date prepared: March 20, 2015

510(k) Owner: Vital Art and Science, LLC
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Name of the Device and Classification

Type of 510(k) Submission:	Traditional
Trade Name:	myVisionTrack® Model 0005
Common Name:	Home vision function monitor
Regulation Number:	21 CFR 886.1330
Regulation Name:	Amsler grid
Regulatory Class:	Class I
Product Code:	HOQ

Predicate Devices:

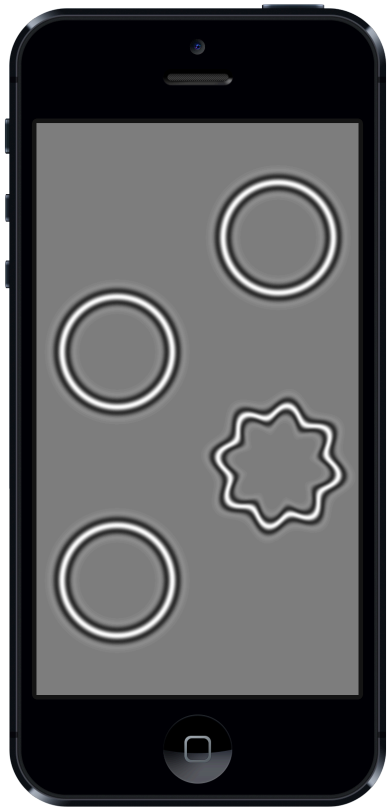
The Vital Art and Science, LLC myVisionTrack® Model 0005 (mVT™) is substantially equivalent to the following predicate medical device:

- myVisionTrack® Model 0003 supplied by Vital Art and Science Incorporated; Perimeter, Automatic, AC-Powered, 21 CFR 886.1605; K121738; Product Code: HPT

Device Description:

The myVisionTrack® Model 0005 is a vision function test provided as a downloadable app on to the user's supplied cell phone or tablet. The myVisionTrack® Model 0005 implements a shape discrimination hyperacuity (SDH) vision test which allows patients to perform their own vision test at home. If a significant worsening of vision function is detected the physician will be notified and provided access to the vision self-test results so that they can decide whether the patient needs to be seen sooner than their next already scheduled appointment.

The test images used by myVisionTrack® Model 0005 are shown below. The distorted version is created by modulating the radius of the circle with a sinusoid. The user is shown four circles and asked to identify the distorted circle



Indications for Use:

The myVisionTrack® Model 0005 is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring progression of disease factors causing metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home.

The myVisionTrack® is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

Indications for Use as compared to the Predicate Device:

The Indications for Use is identical to the Indications for User for the Predicate Device.

Substantial Equivalence Comparison

The myVisionTrack® Model 0005 is a modification to the myVisionTrack® Model 0003 (K121738) which was cleared in February, 2013. The myVisionTrack® Model 0005 has the same intended use and indications for use, principles of operation, and similar technological characteristics as the previously cleared predicate. The major elements of the technology remain unchanged. The target population and the area of vision monitored is identical between the two devices. The vision test algorithm used and the test algorithm implementation is identical between the two devices.

The two devices are identical with the exception of the differences which are as follows:

Hardware Platform and Display Resolution: The myVisionTrack® Model 0003 was delivered as an app already installed on an Apple iPhone 4S device. The myVisionTrack® Model 0005 will be distributed as an app for a user supplied device including the following devices:

iPhone 4s, 5, 5c, 5s, 6, 6+
iPod Touch 4, 5
iPad 2, 3, 4
iPad Air, Air 2
iPad mini, mini 2/3 (retina)
iOS Support is iOS 6, 7, and 8

Some of the older devices have a lower pixels/degree than the previously cleared iPhone 4S, but previously conducted clinical studies on these devices have demonstrated there is no significant difference in the clinical results.
The myVisionTrack® Model 0005 only runs on hardware and operating systems that have been fully validated and approved by Vital Art and Science, LLC. This is controlled by doing a check on start-up of the app and comparing against a list of approved hardware and iOS.

Method Supplied: The myVisionTrack® Model 0003 was supplied with the necessary hardware while the myVisionTrack® Model 0005 will be provided as an app available on the Apple iTunes store. Instructions for how to download, install and unlock the app will be provided on the Rx provided by the Prescribing Doctor through a secure portal. These

printed instructions will also point the user towards Vital Art and Science, LLC's website, where there will be detailed instructions and videos on how to download, install and take the test. The Rx will also have information on how to access our 24/7 support center for any additional help they may need.

Data Upload Capability: The myVisionTrack® Model 0003 was being supplied with a device that was already set-up with a cellular data connection. In the myVisionTrack® Model 0005, the patient will be supplying the Apple device including the connection to the internet.

Number of test circles: The myVisionTrack® Model 0003 was limited to a maximum of 3 displayed test circles by the small display size of the iPhone Models 1 – 3. All of the original development work and initial studies were done on these smaller devices. Since the iPhone 4 the size of the display is such that we can fit in 4 test circles. It is desirable to transition to a 4 circle test because it reduces the "chance level" of the user guessing the correct circle from 33% to 25% and so improves the accuracy of the test. The underlying methodology and science of the test remains unchanged. The only change made here is to change from a "3 alternative forced choice" or 3AFC algorithm to a "4 alternative forced choice" or 4AFC algorithm.

Orientation of Display: In the myVisionTrack® Model 0003 users had been encouraged to test using 2 hands to hold the device in a "landscape" orientation. As Apple has come out with larger devices, such as the iPad and iPad mini, and added more features including the "front facing camera" it has become clear to us that most patients are more comfortable holding the device in a "portrait" orientation. This is the standard orientation for holding the iPhone when making phone calls, and using most other functions.

Method of managing "by Rx Only": The myVisionTrack® Model 0003 was controlled through physical management of the devices themselves. With the change to a downloadable app for the myVisionTrack® Model 0005 a different method is required to limit access to the app to those with a valid prescription, and to insure the test results and alerts are delivered to that prescribing doctor. The method implemented in the myVisionTrack® Model 0005 is to use a 10 digit Rx Code. This code is generated on Vital Art and Science, LLC's secure Portal by the prescribing doctor, or someone on their staff. This is a one-time-use code that is invalid for any additional user once it has been used. The code is printed automatically from the Portal at the time the device is prescribed, and once it is used to unlock the app it provides the connection required to insure that all test results are attributed to that patient, and results delivered to their prescribing doctor.

Who can prescribe: The myVisionTrack® Model 0003 was cleared for Prescription Use only by order of a physician (MD or DO). Since the bulk of eye care is provided by Optometrists (ODs) in the United States, Vital Art wants to allow ODs to prescribe the app as well.

In conclusion, the proposed myVisionTrack® Model 0005 as compared to the already cleared Model 0003 predicate device has:

- Identical indications for use;
- Similar physical composition, in that both use visual testing software delivered on a validated hardware platform and operating system;
- A more traditional prescription method where the doctor delivers a paper Rx with instructions on how to download and install the app instead of delivering a device with the app already installed;
- An identical vision test algorithm, but with the change from 3 to 4 choices of displayed images;
- An identical method of operation for the patient to perform self-testing at home; and
- An identical central monitoring of patient self-test results, with a new method to insure test results and alerts are being delivered only to their prescribing doctor.

Therefore the myVisionTrack® Model 0005 is substantially equivalent to the predicate device.

Performance Data

Verification and validation of the software confirmed that the software performs as intended. A Usability Study was independently performed with 10 subjects (5 normal and 5 with maculopathy) and concluded that subjects could effectively self-test their vision and that they found the device to be user-friendly. Participants ranged in age from 19 to 68. The usability study concluded that with a training session demo, users should not encounter any difficulties completing the self-test. Participants reported no complaints on device or myVisionTrack® Model 0005. All participants did meet the 90% criteria of taking the vision self-test without encountering any issues that prevented them from completing the test. 90% of participants understood how to access the "More" screen and additional functions. 80% were able to complete the vision self-test in less than 10 minutes.

A Cross-sectional Study was also performed with 86 subjects (40 with normal vision and 46 with various types of maculopathy) to do a direct comparison of the myVisionTrack® Model 0003 to the myVisionTrack® Model 0005. The study concluded that the performance of the myVisionTrack® Model 0005 employing a 4AFC testing paradigm is not significantly different from that of myVisionTrack® Model 0003 using a 3AFC testing paradigm. The test results obtained with these two models are comparable with each other. While there is a slight bias of approximately 0.06 logRM (log10 of Radial Modulation amplitude) worse results for the myVisionTrack® Model 0005 measurements compared to myVisionTrack® Model 0003. This bias is not surprising and

it agrees with the design hypothesis that 4AFC paradigm reduces the chance level (lucky guesses) when compared with 3AFC, so that it reduces the likelihood of overestimating patients' ability to detect distortion in a shape discrimination task, which will in fact allow myVisionTrack® Model 0005 to obtain more reliable self-testing results. Additionally 4 patients with maculopathy were tested using an iPod Touch (3AFC), an iPad air (4AFC, circular arrangement of stimulus patterns) and an iPhone 6+ (4AFC, rectangular arrangement of stimulus patterns) to confirm performance across device platforms. The test results demonstrated that the test variability across different devices is comparable or smaller than 0.10 logRM, which is the test variability over time for the mVT™ test. The mean results across all patients are -2.11 logRM, -2.07 logRM, and -2.07 logRM for iPod Touch, iPad air, and iPhone 6+, respectively, which is not significantly different from each other ($F=0.047$, $p>0.95$).